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Regulatory Analysis and Development, PPD  
USDA-APHIS  
Station 3A-03.8  
4700 River Road Unite 118  
Riverdale, MD 20737-1238

Re: Docket No. APHIS-2008-0023  
Importation, Interstate Movement, Release into the Environment of Certain Genetically Engineered Organisms

(I request that this letter be included in the regulatory file as a comment on the above document and docket number.)

Dear Mr. Lambert:

I have read the proposed regulations and accompanying explanation related to Docket No. APHIS-2008-0023. I have been teaching, writing, and lecturing about agricultural biotechnology law and policy issues for more than a decade.

In 1986 and 1987, the US Government and the US National Academy of Science published documents that made the following points that biotechnology:

- is an extension of traditional methods that can produce similar or identical products;
- enables more precise genetic modifications;
- presents no evidence of unique hazards;
- creates risks that are the same in kind as other genetic methods; and
- assessment should be based on the nature of the organism and the environment into which it is introduced, not the method by which it is produced.

Twenty plus years later, after thousands of field tests for agricultural biotechnology and millions of acres of commercial production of biotech crops, the points stated in the Coordinated Framework (1986) and the US-NAS publication (1987) have been reinforced and bolstered. Agricultural biotechnology has proven itself as a beneficial, desirable, and safe technology. Agricultural biotechnology has proven that its crops are simply agricultural crops – corn, wheat, canola, soybeans, plums, papayas, sweet corn, and peppers.

Despite this understanding from the beginning and despite these twenty plus years of experience, APHIS has proposed new regulations that continue to single out biotech agriculture for unique and burdensome regulations. While APHIS states in the explanation of the proposed regulations that the “mere act of genetic engineering does not trigger regulatory oversight or mean that a GE organism will pose risks as a plant pest or noxious weed,” the scope of the proposed regulation includes all biotech agriculture as within the regulation until APHIS determines that the biotech crop is not a plant pest or a noxious weed. No other crops from any other breeding method are within the scope of this regulation. No other crops from any other breeding method must await APHIS determinations before these crops can be imported, moved in interstate commerce, or be released into the environment. APHIS does have the regulatory authority to classify crops from other breeding methods as plant pests or noxious weeds but these crops are presumed to be agricultural crops until APHIS reclassifies them as plant pests or noxious weeds. APHIS does not treat agricultural biotechnology the same as crops from other breeding methods. APHIS does not presume that biotech crops are simply agricultural crops until APHIS reclassifies a particular crop as a plant pest or a noxious weed.

APHIS, and other regulatory agencies of the United States, should abandon the scientifically unjustified and discriminatory bias against agricultural biotechnology as reflected in the proposed regulation. APHIS should regulate agricultural biotechnology crops in a manner no different than it regulates crops from any other breeding method.

Even assuming that APHIS will not change its fundamentally invalid bias about agricultural biotechnology, APHIS could draft regulations that streamline regulatory procedures and that reduce to a minimum the regulatory burdens and costs. Even granting the broad scope of the proposed regulation, APHIS could use its regulatory authority to build upon the correct points from 1986/1987, the twenty plus years experience, and the modifications to APHIS regulations from 1993 and 1997 to promote agricultural biotechnology as a worthwhile, beneficial, safe, and needed technology for agriculture.

Instead, these proposed regulations do not reduce regulatory burdens and promote agricultural biotechnology. Allow me to give three examples.

- The proposed regulations abandon the streamlined notification procedures (90% of present regulation) to impose a permit system upon every movement and field trial of agricultural biotechnology. By so doing, the proposed regulations do away with simplified regulatory procedures for agricultural biotechnology. I suggest that APHIS reconsider this decision and that APHIS expand streamlined, simplified procedures. APHIS created the streamlined notification procedures in 1993/1997 because of experiences previously gained. APHIS today in 2008 has many more experiences and much greater data to give confidence in agricultural biotechnology. APHIS should be expanding, rather than reducing simplified procedures, in the proposed regulation.

- Despite the fact that the proposed regulations will grandfather transgenic crops that have already gained nonregulated status from inclusion within the proposed regulations, there are no new or additional categorical exclusions. In light of the twenty years of positive and beneficial experiences with virus-resistant papaya, herbicide-tolerant crops, and Bt crops, APHIS should be creating categorical exclusions for these well-studied and well-understood transgenic crops. APHIS should not be wasting regulatory resources or inviting judicial challenges to fears about minuscule low-level presence (trace

presence) of transgenic crops. APHIS should be encouraging nonregulated status through categorical exclusions.

- Despite the well-studied and well-understood transgenic crops, the proposed regulations provide no avenue for simplified and sensible recognition of approvals for transgenic crops by the regulatory systems of other nations. Hence, for example, rather than recognizing the excellent regulatory work of the Indian regulatory system on Bt-eggplant, APHIS will subject this crop to APHIS regulation as if APHIS knew nothing about Bt-crops and as if APHIS had no trust in another nation's regulatory system. APHIS should be reducing repetitive regulatory burdens rather than adopting and adding repetitive regulatory burdens.

Instead of easing the regulatory burdens upon agricultural biotechnology, APHIS says that it must keep pace with changes in technology and respond to Section 10204 of the 2008 Farm Bill. APHIS' bias towards more and burdensome regulation is evidenced strongly by the reference to Section 10204 which refers to an APHIS drafted document about "Lessons Learned and Revisions under Consideration for APHIS' Biotechnology Framework." Although I do not know the origin of Section 10204, I would be utterly surprised and foolishly naive if I thought anything other than that APHIS itself is the origin of Section 10204 as a way to bolster its bias for additional regulations on agricultural biotechnology. [I add that Section 10204, by its own language, gives the Secretary authority to regulate "as the Secretary considers appropriate."] APHIS in this proposed rule considers it appropriate to exercise its discretion to impose additional regulations. APHIS should do just the opposite to this proposed rule – i.e. APHIS should consider it appropriate to draft a proposed rule that reduces regulatory burdens on agricultural biotechnology.

Why does it matter that APHIS abandon its scientifically unjustified and discriminatory bias against agricultural biotechnology? Why does it matter that APHIS promote agricultural biotechnology by streamlining regulatory procedures and reducing regulatory burdens and costs?

- By its present bias and increased burdens, APHIS is failing to assist the American public (and the world public) to improve their scientific literacy and is failing to promote a positive attitude toward science. By its present bias and increased burdens, APHIS is encouraging, even if it is indirect and unintentional, the anti-science agenda of many activist groups and the fears that these groups spread among the public.

- By its present bias and increased burdens, APHIS is imposing a misallocation of resources upon the agricultural research community. While this misallocation of resources (increased time and costs) is troublesome for private companies, public researchers are particularly harmed. Publicly-funded agricultural research does not have the resources in personnel and money to devote to unnecessary and unneeded regulation.

- By its present bias and increased burdens, APHIS is slowing the adoption of a worthwhile, beneficial, safe, and needed technology for agriculture. Most agricultural scientists and many agricultural economists have been clamoring for greater investment in and utilization of science and technology in agriculture to increase productivity in order to satisfy the demands for food, fibers, fuels, medicines, and bioremediation.

This bullet point is well-stated by Agenda 21 from Rio de Janeiro (1992) in Paragraph 16.1 which states, “ ... By itself, biotechnology cannot resolve all the fundamental problems of environment development, so expectations need to be tempered by realism. Nevertheless, it promises to make a significant contribution to enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. ...”

Note that Agenda 21 calls for expectations tempered by realism, not expectations burdened by excessive, costly regulations. Twenty plus years of excellent experience have provided us the realism. APHIS should respond by promoting agricultural biotechnology like any other crop breeding method.

- By its present bias and increased burdens, APHIS is indirectly sustaining and continuing conditions of poverty and food insecurity for the poorest of the world. Subsistence and small farmers of the world need access to science and the agricultural crops from agricultural biotechnology. APHIS slows and (maybe even) stalls this access because of the bullet points immediately preceding this point. I am troubled deeply by this indirect consequence from the attitude and actions of APHIS.

- By its present bias and increased burdens, APHIS is undermining agricultural productivity at a time when increased agricultural productivity is a necessity if the world is to meet the food, feed, fiber, and fuel demands that the people of the world are placing upon agriculture. Moreover, as APHIS with this proposed regulation undermines agricultural productivity, APHIS is also undermining the technological advances that likely will allow agriculture to reduce its environmental footprint so that agriculture contributes in a sustainable way to the environmental values. This proposed regulation thus does two harms – reduced productive and less sustainable protection for the environment.

Sincerely yours,

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